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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/588,637 01/19/96 BARBOUR

A 454312-2420

020999
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HM12/0522

EXAMINER

RYAN, V

ART UNIT

PAPER NUMBER

17

1641

DATE MAILED:

05/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/588,637	Applicant(s) Barbour et al
Examiner V. Ryan	Group Art Unit 1641

Responsive to communication(s) filed on Jan 13, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-4, 6-10, 12, and 13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-4, 6-10, 12, and 13 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

The Examiner acknowledges receipt of the amendment filed January 13, 2000.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In this application:

claims 1-4, 6-10, 12 and 13 are now pending and under examination.

Response to Amendment

- (1) The objection to the drawings under 37 CFR 1.84 or 1.152 for the reasons stated on PTO 948.
- (2) The rejection of claims 1-4, 6-10, 12 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512 is maintained. However, claims 1, 3 and 7 of US Patent #5,688,512 are no longer included in the rejection. A modified rejection is set forth below.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-10, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512 in view of Bergstrom et al (US Patent #5,523,089) or SN Cohen.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed to a method for inducing an immunological response in a mammalian host susceptible to Lyme disease or *Borrelia burgdorferi* infection comprising "mucosally" administering substantially pure OspA. US Patent #5,688,512 claims a method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to

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Lyme disease comprising administering a vaccine comprised of substantially pure OspA.

Bergstrom et al (US Patent #5,523,089) teaches the various routes of administration (oral, subcutaneous, intracutaneous, intramuscular, nasal or rectal) as alternative means of administering the composition comprised of OspA. (See especially column 18, lines 16-35).

Cohen SN (Immunization. Chapter 43 in: *Basic & Clinical Immunology*, 3rd ed. Fudenberg HH, Stites DP, Caldwell JL, Wells JV (editors). Lange Medical Publications, 1980) teaches various routes of administering vaccines such as subcutaneous, intradermal, intramuscular and oral. (See especially Table 43-3).

Therefore, given that the prior art recognized various routes of administering immunogenic compositions, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the composition orally or subcutaneously as these are recognized routes of administering compositions for inducing an immune response.

Applicant contends that claim 2 of US Patent #5,688,512 is generic since it is directed to a method of inducing a protective

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immunological response by administering the vaccine comprising substantially pure OspA, whereas the claims of the instant application are directed to a method of mucosal administration in order to induce an immunological response.

However, while the claims of the instant application are directed to mucosal administration, the prior art and the parent application 08/079,601 (US Patent #5,523,089) teach the various routes of administration (oral, subcutaneous, intracutaneous, intramuscular, nasal or rectal) as alternative means of administering compositions to induce an immune response. (See especially column 18, lines 16-35). Therefore, the obvious-type double patenting rejection is maintained.

(3) The rejection of claims 1-4, 6-10, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Bergstrom et al is withdrawn.

(4) The rejection of claims 1-4, 6-10, 12 and 13 under 35 U.S.C. 112, second paragraph is withdrawn.

(5) The rejection of claims 1-4, 6-10, 12 and 13 under 35 U.S.C. 103 as being unpatentable by Burgess is withdrawn.

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in

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correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703) 305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703) 308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
April 2000
Ryan/vr

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1641